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Int. Cl. ⁽⁵¹⁾ A011; B65b

Application Number ⁽²¹⁾ 50285/69.

Lodged ⁽²²⁾ 10th February, 1969.

Complete Specification
entitled ⁽⁵⁴⁾ SUTURE PACKAGE.

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Related Art ⁽⁵⁶⁾ 268503(17984/62)
280888(45647/64)
46464/64

57.4; 49.3; 87.4.
57.4; 87.4.
57.4; 48.5; 87.4.

The following statement is a full description of this invention, including the best method of performing it known to us:

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F. D. Atkinson, Government Printer, Canberra

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The present invention relates to packages for surgical sutures in coil form, more particularly to relatively stiff sutures of polymeric monofilaments, and the like, packaged in this way. When the term suture or sutures is used in this application, it shall mean elongated strands suitable for suturing, ligating, or other surgical procedures and shall include those strands commonly called sutures and ligatures.

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Heretofore, relatively stiff monofilament sutures have been packaged in various ways intended to minimize the formation of kinks or sharp bends in the suture strand due to packaging. For instance, the suture has been wound upon circular reels and various other attempts have been made to coil the suture smoothly and in such a way that no kinks will be formed. Necessarily, when the suture has been coiled in this manner, it has been retained in the package in coiled form for an extended period of time prior to use. As a result, the suture strand adopts a set configuration based upon the form in which it was coiled, even when it is unwound or removed from the package. Thus when a suture, which has been coiled in circular form on a reel, is removed from the reel, it will tend to return or snap back into a circular configuration. When the suture is attached to a needle, as it normally is for suturing purposes, the surgeon must prevent the suture strand from coiling up against the needle and interfering with the surgical procedure. This is a difficult problem because it is almost impossible to prevent sutures of this type from assuming a set during packaging.

We have discovered that this tendency of the suture to assume a configuration approximating the shape in which it is packaged can actually be an important advantage, and have devised a novel package for this purpose. In accordance with our invention, the shape or configuration in which the suture is retained in the package is carefully controlled to give a particular configuration to the suture

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after it has been withdrawn from the package which will assure that the suture does not interfere with the surgical procedure and, in fact, is easier to handle by virtue of the fact that it has a definite shape. This is accomplished by winding the suture in the form of a coil comprising a multiplicity of figure eight convolutions which are superimposed one upon the other in successive layers with the convolutions disposed in sequence from one end of the suture to the other. Each of the figure eight convolutions comprises a centrally located suture crossing and opposed loops on each side of the crossing with the loops also integral with the suture portions forming the crossings. As a result, the coils are maintained in sequence and in layers at the suture crossings since these crossings prevent adjacent convolutions from telescoping or entangling with one another. When the suture is coiled in this manner, and removed from the package by drawing upon one of its ends, it assumes a non-entangling sinusoidal configuration of successive positive and negative lobes. When the suture is held by one end it remains extended in this form and has no tendency to coil up again adjacent the needle to which it is attached.

In the preferred form of our invention, the suture is attached to a curved suturing needle, and the needle with the suture end attached thereto is retained in the package in such a way that when the suture is removed therefrom, as described above, the point of the needle is directed away from the next adjacent suture lobe, thereby assuring that the

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suture will trail behind the needle point during surgery. To accomplish this the curved needle and the suture end attached thereto are retained in the package in such a way that the curve of the needle and the suture end attached thereto generally follows the curved configuration of the suture coil. The suture end is arranged so that it generally continues to follow the shape of the figure eight coil and the needle attached thereto is positioned in such a way that it appears to be a continuation of the coil configuration.

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In the package of this invention the suture is held in the desired coil form by a retainer which, in turn, is packaged in a hermetically sealed outer container such as an envelope adapted to be opened by stripping or any other suitable technique. The retainer is such that the suture may be positioned easily therein in successive layers of figure eight convolutions, retained in the desired coil form when the outer container is opened, and then dispensed easily from the retainer merely by drawing upon an exposed end of the suture or a needle attached thereto.

The suture may be wound in figure eight form on a jig provided for this purpose and then placed in the retainer, or it may be wound as it is being positioned in the retainer by employing a jig which cooperates with or penetrates a portion of the retainer as will be described more fully hereinafter. In either case the retainer is adapted to be closed easily and locked together to hold the coil convolutions in the desired relationship in the package. Then the retainer with the suture in position therein is hermetically sealed in the outer container.

Preferably, the retainer of the package of this

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invention comprises first and second panels foldably connected to one another and adapted to be folded together and superimposed with the figure eight suture coil between them and one end of the suture and the needle, when a needle is attached thereto, extending out from between the panels at one end of the retainer. Preferably also the retainer includes a third panel foldably connected to the first panel along another one of its edges. In this form, the suture coil is positioned on the first panel and the second panel is folded directly down over the coil. In this position the second panel presents a locking tab which enters into alignment with a locking slot defined along the fold line between the first and third panels. This tab and slot are so designed that when the third panel is folded down over the second panel the tab automatically enters the slot and becomes locked in position therein. Furthermore the locking tab remains in the slot to hold the second panel in position over the suture coil even when the third panel is again unfolded. It therefore is preferred when the suture is packaged in this manner to fold the suture end and the needle attached thereto down over the second panel so that it will be held in position in the retainer by the third panel when it is folded down to lock the second panel in position. Locking means preferably is provided for holding the third panel over the second panel to retain the suture end in position between the second and third panels. This is particularly important when a curved needle is attached to the suture end and the needle and suture are carefully

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arranged to continue the shape of the figure eight convolutions of the coil, as described hereinbefore.

In the preferred form of this invention, the suture retainer is generally rectangular in shape and the second and third panels are foldably connected to opposite longitudinal edges of the first panel. Preferably, also, the second panel presents a notch at one end to guide the free end of the suture as it and the needle are folded down over the second panel. For best results, a cooperating tab and notch are provided along the free edge of the third panel and along the fold line between the first and second panels, respectively, for locking the third panel in position over the second panel when all the parts of the retainer are folded together.

Other and further advantages of this invention will appear to one skilled in the art from the following description and claims taken together with the drawings wherein:

Fig. 1 is a schematic top plan view, partly in section, showing a needled suture being wound on a jig in a figure eight suture coil according to this invention.

Fig. 2 is a schematic top plan view of a suture retainer according to one embodiment of this invention with its parts unfolded and a needled suture coil partly in position thereon.

Fig. 3 is a similar top plan view of the retainer of Fig. 2 after the second panel has been folded down to hold the suture coil in position, and showing the way in which the curved needle and the suture end attached thereto are folded down and positioned over the coil to resemble

the configuration of the coil.

Fig. 4 is another top plan view of the retainer of Fig. 2 showing how the locking tabs on the second panel enter the locking slots along the fold lines at the edge of the first panel when either of the third or fourth panels are folded down over the second panel.

Fig. 5 is a view in perspective of the suture retainer of the preceding figures after all of the panels have been folded together.

Fig. 6 is an enlarged schematic view partly in section and partly in elevation taken along the line 6-6 of Fig. 5.

Fig. 7 is a view in perspective of the retainer of the preceding figures showing how the suture may be dispensed easily merely by drawing it from one end of the retainer by the needle attached to the free-end of the suture after the third and fourth panels have been folded open.

Fig. 8 is a schematic plan view showing the sinusoidal shape of the suture after it has been withdrawn from the package, and the disposition of the curved needle with respect thereto.

Fig. 9 is a schematic view in perspective, partially developed to show how the figure eight convolutions are arranged in the coil in successive layers.

Fig. 9a is a greatly enlarged view in perspective of the central portion of the figure eight suture coil showing the layer-like relation of the successive convolutions at the suture crossings.

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Fig. 10 is a schematic plan view, partly in section, showing an unfolded suture retainer according to another preferred embodiment of this invention.

Fig. 11 is a similar plan view of the retainer of Fig. 10 showing how a suture may be wound in a figure eight coil according to this invention on a pair of opposed winding fixtures inserted through slots provided for this purpose in the first panel of the retainer.

Fig. 12 is a schematic plan view of the retainer and suture of Fig. 11 showing the second panel folded down over the first panel and with the curved needle and suture end positioned over the second panel.

Fig. 13 is a view in perspective of the suture retainer of Figs. 10-12 with all of its parts folded together and locked in position.

Fig. 14 is an enlarged schematic view partly in section and partly in elevation taken along the line 14-14 of Fig. 13.

Fig. 15 is a schematic view in perspective of a complete suture package according to this invention showing the retainer and suture coil in position and hermetically sealed within an outer container which is adapted to be opened along a tear line provided for that purpose.

Fig. 16 is a view in perspective similar to that of Fig. 15 and showing the suture retainer being removed from the outer container after one end of the container has been torn from the package.

Fig. 17 is a view in perspective showing how the retainer of Figs. 10-14 is adapted to be held by one hand and opened by the other.

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Fig. 18 is a view in perspective showing how the needle and suture may be removed easily from the retainer after the third panel thereof has been unlocked and unfolded as shown in Fig. 17.

Referring to the drawings, Fig. 1 shows a monofilament suture 20 according to this invention being wound upon a pair of opposed winding fixtures 21 presented from a jig 22 provided for this purpose. A curved suture needle 23 was attached to one end of this suture prior to winding it upon the fixtures 21. The suture 20 is wound on the fixtures 21 in the form of a coil comprising a multiplicity of figure eight convolutions each of which is in the form of a centrally located suture crossing 25 with opposed loops 26 integral with the suture portions forming the crossings 25. As shown most clearly in Figs. 6, 9 and 9a, this results in a figure eight coil wherein the convolutions are superimposed one upon the other in successive layers 27 at the suture crossings 25 with the convolutions disposed in sequence from one end of the suture to the other. Fig. 9a, in particular, shows the layer-like relationship of the suture convolutions at the suture crossings 25 and the way in which the suture crossings prevent successive convolutions from telescoping with one another at the crossings.

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21 In Figs. 2-7 of the drawings there is shown a suture retainer according to one embodiment of this invention which comprises four panels, i.e. a first panel 30 on which the suture coil is positioned, a second panel 31 foldably connected to one end of the first panel 30, and third and fourth panels 32 and 33, respectively, each of which is foldably connected to an opposite longitudinal edge of the first panel 30. The retainer may be formed from any suitable relatively stiff sheet material, such as conventional paper-board or the like. Preferably, definite fold lines are provided where the first panel is connected to each of the other panels such as by scoring the sheet material from which the retainer is made as indicated by the interrupted lines in the drawings. Thus, the retainer of this invention may be formed or cut from a single sheet of material to form a suitable blank such as is shown in Fig. 2, and in Fig. 10 which illustrates a somewhat different embodiment of this invention.

The figure eight suture coil is positioned centrally on the first panel 30 of the retainer as shown in Fig. 2 with the needle 23 and the suture end attached thereto extending out beyond that end of the first panel 30 opposite to that of the second panel 31. Then the second panel 31 is folded down over the suture coil.

The second panel 31 presents a locking tab 34 at each of its longitudinal edges, each of which is adapted to enter into alignment with a corresponding locking slot 35 defined along one of the fold lines between the first

panel 30 and the third or fourth panel. For instance, the lower-most locking tab 34 on the second panel will be aligned with the locking slot 35 between the first and third panels 30 and 32. As a result, when the third panel 32 is folded down over the second panel 31 as shown in Fig. 4, the locking tab 34 at the lower edge of the second panel 31 will automatically enter the locking slot 35 between the first and third panels. The same is true as to the other locking tab 34 and the locking slot 35 between the first and fourth panels 30 and 33. Thus, the second panel 31 is automatically locked in position over the suture coil by the locking tabs 34 at both of its edges when the third and fourth panels both are folded down over one another as shown in Fig. 5. As illustrated in Fig. 7, even after the third and fourth panels are unfolded completely, the second panel remains locked in position over the suture coil by virtue of the continuing engagement between the tabs 34 and the slots 35.

A notch or recess 36 is provided at the outer end of the second panel 31 to help guide the free end of the suture 20, i.e. that attached to the needle 23, in folding the suture and the needle down over the second panel after the second panel has been positioned over the coil, as shown in Fig. 3. Fig. 3 also shows how the suture end is carefully curved back and superimposed over the second panel to assume a position generally continuing the figure eight convolution to which it is attached with the needle 23 generally following the curved configuration of the coil.

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35 Fig. 8 clearly shows the type of suture configuration which is imparted to the suture 20 by packaging it in this manner. As explained hereinbefore, after it is withdrawn from the package the suture 20 of this invention assumes a non-entangling sinusoidal configuration of successive positive and negative lobes 37 with the point of the needle 23 directed away from the next adjacent suture lobe. Furthermore the curved needle 23, at this point, is disposed in such a way that it appears to continue the sinusoidal shape of the suture. The suture now tends to retain this sinusoidal shape and has no tendency to snap back into its original coiled form. As a result of this and the fact that the point of the needle 23 is directed away from the next adjacent suture lobe 37, it is assured that the suture will trail behind the needle point during surgery and will not interfere with the surgical procedure in any way. The sinusoidal lobes 37 of the suture may initially be less pronounced than shown schematically in Fig. 8, or may become somewhat less pronounced after the suture is removed from its retainer. However, the generally sinusoidal shape of the suture 20 will remain even though the lobes 37 are a good deal more shallow than shown in Fig. 8.

7 Figs. 10-18 illustrate a preferred embodiment of the package of this invention wherein the suture retainer is rectangular in shape and comprises only three panels, i.e. 18 a first panel 40 on which the suture coil is first positioned and second and third panels 41 and 42, respectively which fold down over the coil. The second and third panels 41

and 42 are foldably connected to the first panel 40 along its opposite longitudinal edges. A unique feature of this embodiment is that a pair of spaced winding openings 43 are provided in the first panel 40 for receiving a corresponding pair of hemicylindrical winding fixtures 44. Thus, the suture 20 is positioned in the retainer by first placing the first panel 40 over the winding fixtures 44 so that the fixtures protrude through the panel roughly as illustrated in Fig. 10. Then, the suture 20, with or without an attached needle 23, may be wound in the form of the figure eight coil of this invention, in the manner described in connection with the preceding figures, with the result indicated in Fig. 11.

For maximum efficiency in completing the package after the suture has been wound on the fixtures 44 protruding through the first panel 40 of the retainer in the foregoing manner, the fixtures may be retractable into a jig, not shown, on which the retainer is positioned. If necessary, however, the retainer merely may be lifted slightly off the fixtures 44 to allow the second and third panels 41 and 42 to be folded down in position over the coil. In this embodiment of the invention, only one locking tab 45 is employed to hold the second panel 41 in position over the coil. This tab 45 is located at the free longitudinal edge of the second panel 41 and is adapted to enter into alignment with and engage a corresponding locking slot 46 along the fold line between the first and third panels 40 and 42, after the second panel 41 has been folded down over

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the coil and when the third panel 42 has been folded down over the second panel, as illustrated in Figs. 12 and 13.

As shown in Fig. 11, after the desired figure eight coiled configuration of the suture is positioned over the winding fixtures 44 protruding through the first panel 40, the curved needle 23 and the suture end attached thereto are left extending over and beyond one end of the first panel 40. Fig. 12 illustrates how this suture end 20 is curved back and superimposed over the second panel 41 to assume a position generally continuing the figure eight convolution to which it is attached with the needle 23 generally following the curved configuration of the coil. To guide the suture end in folding it in this manner, a curved notch 47 is provided in the end of the second panel 41 at the dispensing end of the retainer. The second panel 41 also is foreshortened at the dispensing end of the retainer to facilitate folding the suture end 20 in the shape of the figure eight coil. After the needle 23 and suture end 20 have been positioned over the second panel 41, roughly as shown in Fig. 12, the third panel 42 is folded down over the needle, both to automatically lock the second panel 41 in position and to retain the needle 23 firmly between the second and third panels. For this purpose, a locking tab 48 is provided at the free longitudinal edge of the third panel 42. This tab 48 is adapted to enter into a locking slot or notch 49 in the form of a rectangular opening centered on the fold line between the first and second panels 40 and 41. The locking tab 48 is cut with inclined edges. This locking tab 48 is adapted to be pressed into the rectangular notch 49

and becomes locked therein because it is cut with inclined edges and is wider than the notch 49 at its extremities. However, the tab 48 can be removed fairly easily from the notch 49 by the fingers of the user.

Fig. 15 illustrates how the folded retainer of Figs. 10-14, with the coiled suture 20 positioned therein, is packaged in an outer hermetically sealed container or envelope 50 which possesses a tear line 51 at one end for opening the package when it is desired to obtain access to the suture. This package and retainer are designed so that when the end of the envelope is removed by tearing as described, the retainer may be removed from the envelope 50 by one of its ends, as shown in Fig. 16, and then gripped at its other end for opening. The third or top panel 42 of the retainer is relieved or designed with a cut-out 52 at the end opposite to that from which the suture will be dispensed, to allow the user to grasp the retainer by direct contact with the first and third panels 40 and 41, as shown at the left of Fig. 17. As a result, the retainer may be opened easily by lifting the tab 43 from the locking notch 49 with the fingers of the other hand. As for the embodiment of Figs. 1-7, the tab 45 remains locked in the slot 46 to retain the second panel 41 in its folded position even after the third panel 42 is unfolded. When the third panel 42 is unfolded, as shown in Fig. 18, the needle 23 and suture end are exposed on the second panel and the suture may be removed easily from the retainer merely by grasping the needle and drawing the suture outwardly from the notched end

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To assist in positioning the curved needle 23 over the second panel 41 of the retainer, a curved slot 53 is provided in the second panel which tends to cause a corresponding curved ridge to be formed in the second panel 41 when it is folded down over the suture coil. The needle then may be located against the ridge. In fact, the point of the needle 23 may be inserted in a small hole provided for this purpose at one end of the ridge or slot 53.

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Having now described the invention in specific detail and exemplified the manner in which it may be carried into practice, it will be readily apparent to those skilled in the art that innumerable variations, applications, modifications, and extensions of the basic principles involved may be made without departing from its spirit or scope. For instance, even though the package of this invention is particularly useful in connection with the packaging of relatively stiff monofilament sutures, it may conveniently be used in the packaging of surgical sutures of relatively flexible materials such as silk, cotton, etc., particularly when suture retainers of the type shown in the drawings are employed.

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The claims defining the invention are as follows:-

1. A suture ^{assembly} ~~package~~ which comprises a relatively stiff suture adapted to assume a set configuration determined by the physical configuration in which it is positioned for an extended period of time, said suture being wound in the form of a coil comprising a multiplicity of figure eight convolutions each of which comprises a centrally located suture crossing and opposed loops on each side of said crossing and integral with the suture portions forming said crossing, the suture crossings of successive figure eight convolutions being superimposed one upon the other to dispose the convolutions in successive layers, a curved suturing needle affixed to one end of said suture with the curve of said needle and the suture end attached thereto being disposed to generally follow the curved configuration of the suture coil, and retaining means holding the suture and needle in the aforesaid positions, said suture after being maintained in said position for an extended period of time

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being adapted to be withdrawn from said retaining means to assume a non-entangling sinusoidal configuration of successive positive and negative lobes with the point of said needle directed away from the next adjacent suture lobe, thereby assuring that the suture will trail behind the needle point during surgery.

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2. A suture ^{assembly} package according to Claim 1,

wherein said retaining means comprises first and second panels adapted to hold the suture coil between them, and means associated with said panels for holding the panels together.

3. A suture ^{assembly} package according to Claim 2,

wherein the needle and the suture end attached thereto extend outwardly from between said first and second panels and said suture end is curved back and superimposed over said panels to assume a position generally continuing the figure eight convolution to which it is attached and with said needle generally following the curved configuration of said coil.

4. A suture ^{assembly} package according to Claim 3,

which comprises a third panel adapted to be folded down over said needle and suture end to hold them in the aforesaid position over said first and second panels.

assembly
5. A suture ~~package~~ which comprises a suture wound in the form of a coil comprising a multiplicity of figure eight convolutions each of which comprises a centrally located suture crossing and opposed loops on each side of said crossing and integral with the suture portions forming said crossing, the suture crossings of successive figure eight convolutions being superimposed one upon the other to dispose the convolutions in successive layers, and a suture retainer comprising first and second panels foldably connected to one another along a common edge and adapted to be folded together and superimposed with the figure eight suture coil between them, and ~~holding~~ means for holding the panels in superimposed relation to retain said coil in position therebetween, said figure eight coil being retained between said folded first and second panels with a free end of said suture extending outwardly from between the panels, whereby said suture may be dispensed without fear of entanglement by drawing it outwardly from between said panels by said free end.

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assembly

6. A suture ~~package~~ according to Claim 5,

which also comprises a third panel foldably connected to said first panel along another edge of said first panel, said suture coil being positioned on said first panel and said second panel being folded down over said coil, said second panel presenting a locking tab along a free edge which enters into alignment with a locking slot defined along the fold line between said first and third panels when said second panel is folded down over said first panel, said locking tab being adapted to enter said locking slot when said third panel is folded down over said second panel, thereby locking said second panel in position over said coiled suture and said first panel to hold the suture coil between said first and second panels.

assembly

7. A suture ~~package~~ according to Claim 6, wherein

the free end of said suture is curved back over said second panel to assume a position lying between said second and third panels and means is provided for locking said third panel over said second panel to hold the suture end in position.

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8. A suture ~~package~~ according to Claim 6, wherein

the second panel is foldably connected to said first panel at one end of the sleeve, said third panel is foldably connected to said first panel along one longitudinal edge of said first panel, and said sleeve also comprises a fourth panel foldably connected to said first panel along its opposite longitudinal edge, said second panel presenting a second locking tab which enters into alignment with a corresponding locking slot defined along the fold line between said first and fourth panels when said second panel is folded down over said first panel and said second locking tab being adapted to enter said second locking slot when said fourth panel is folded down over said second panel thereby locking said second panel at each of its longitudinal edges.

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9. A suture ~~package~~ according to Claim 6, wherein

said second panel is foldably connected to one longitudinal edge of said first panel and said third panel is foldably connected to the opposite longitudinal edge of said first panel.

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10 ~~th~~. A suture ^{assembly} package substantially as illustrated in the accompanying drawings and substantially as hereinbefore described by reference thereto.

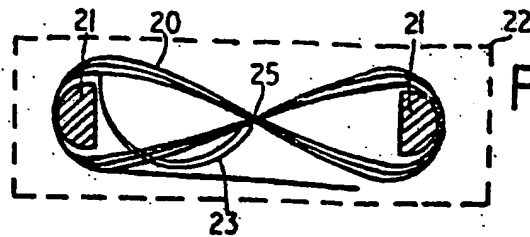
DATED the 6th day of February, 1969.

ETHICON, INC.
By their Patent Attorney:

George H. Frazer

OF GRIFFITH, HASSEL & FRAZER.

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FIG. 1

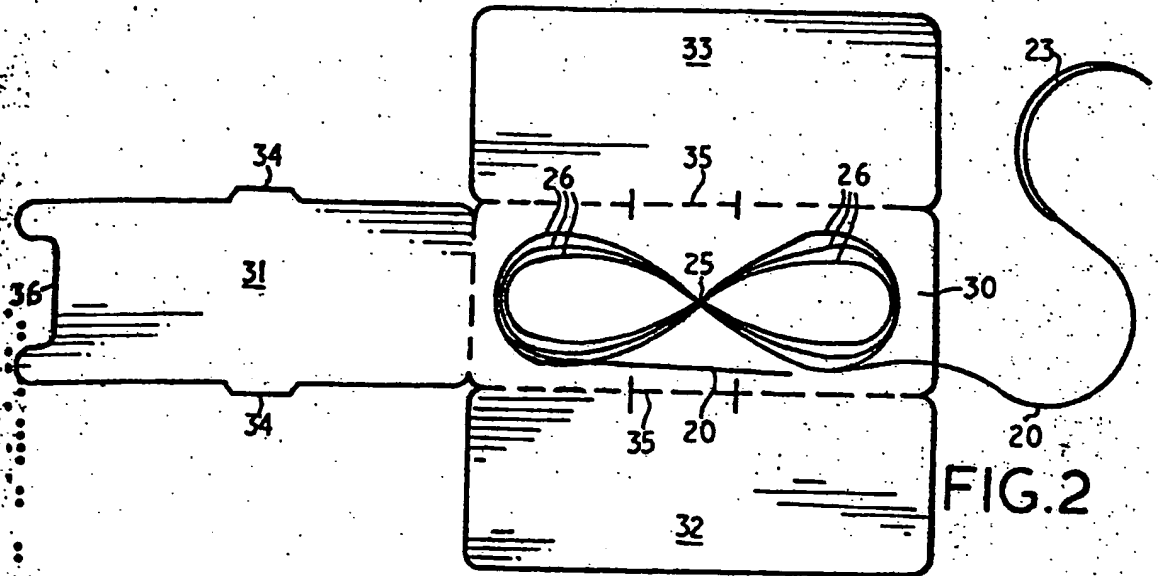


FIG. 2

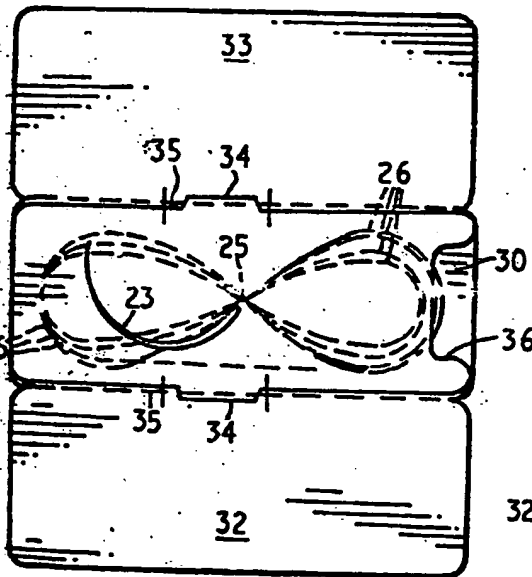


FIG. 3

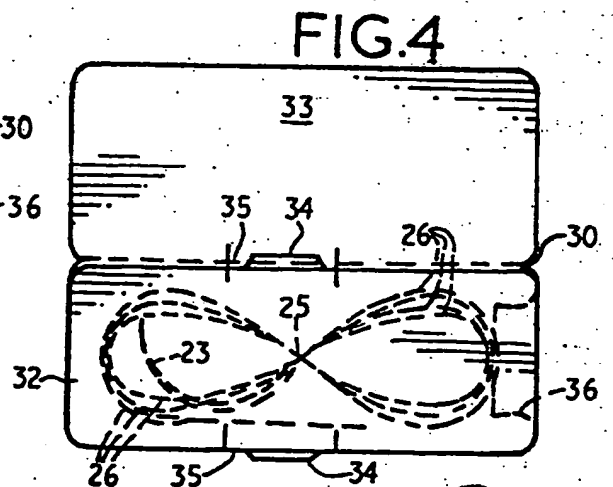


FIG. 4

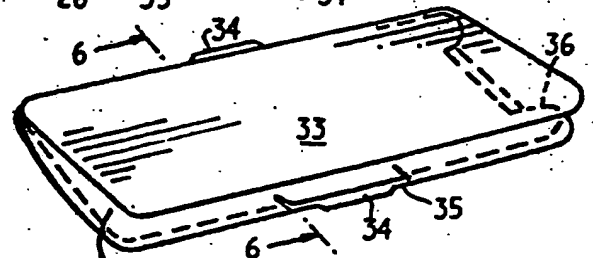


FIG. 5

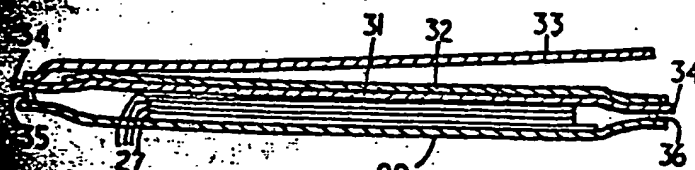


FIG. 6

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10 ~~18~~. A suture ^{assembly} ~~package~~ substantially as illustrated in the accompanying drawings and substantially as hereinbefore described by reference thereto.

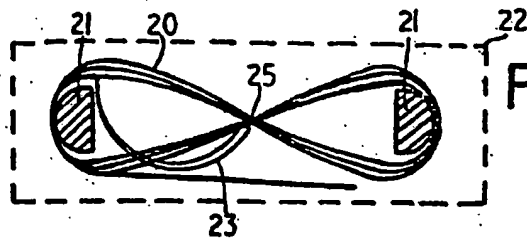
DATED the 6th day of February, 1969.

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FIG. 1

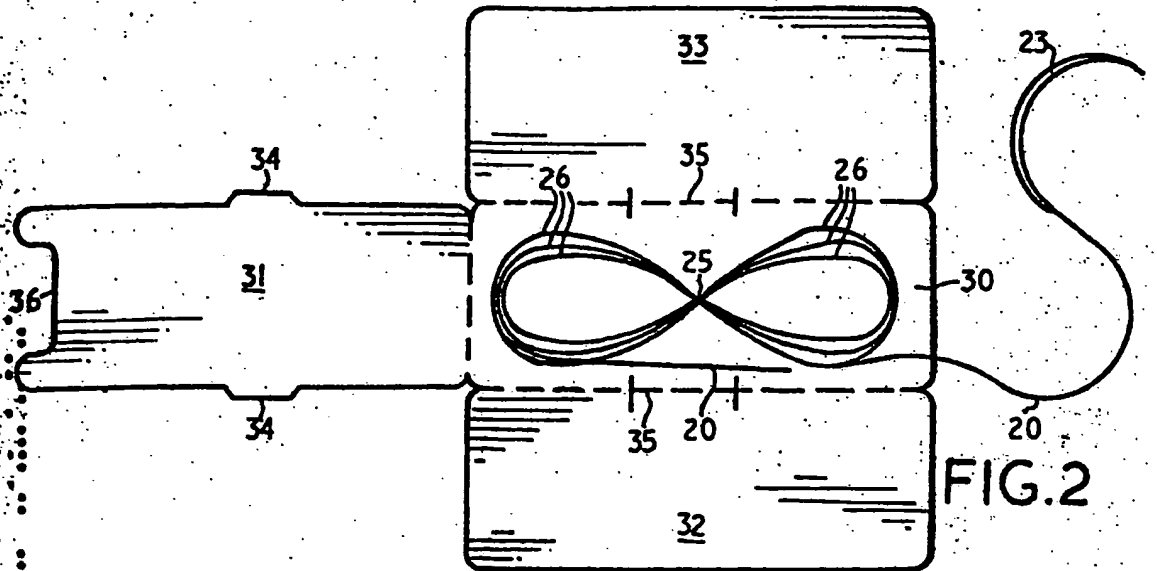


FIG. 2

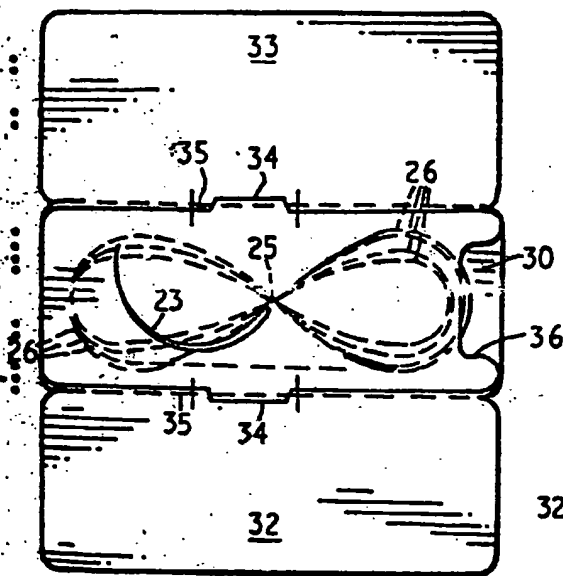


FIG. 3

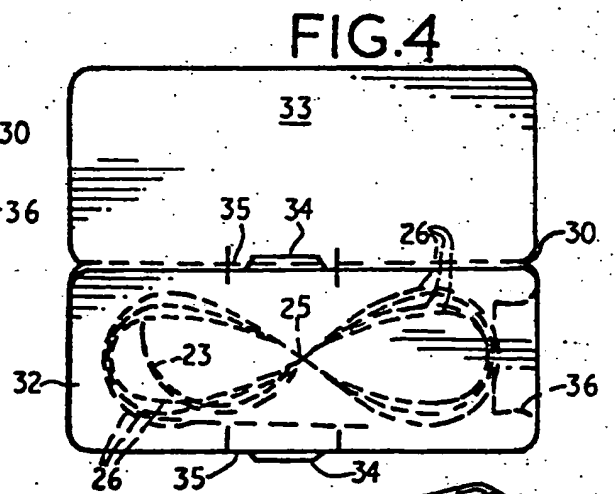


FIG. 4

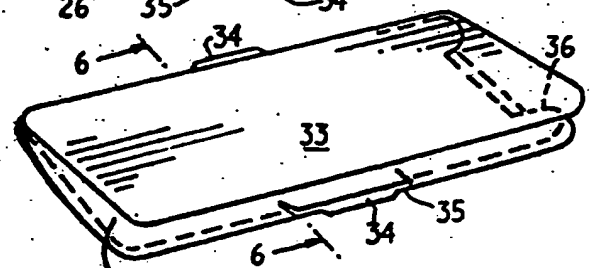


FIG. 5

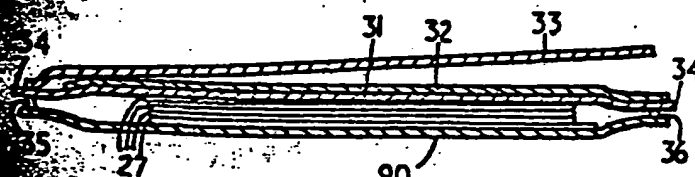


FIG. 6

50,285/69
FIG.7

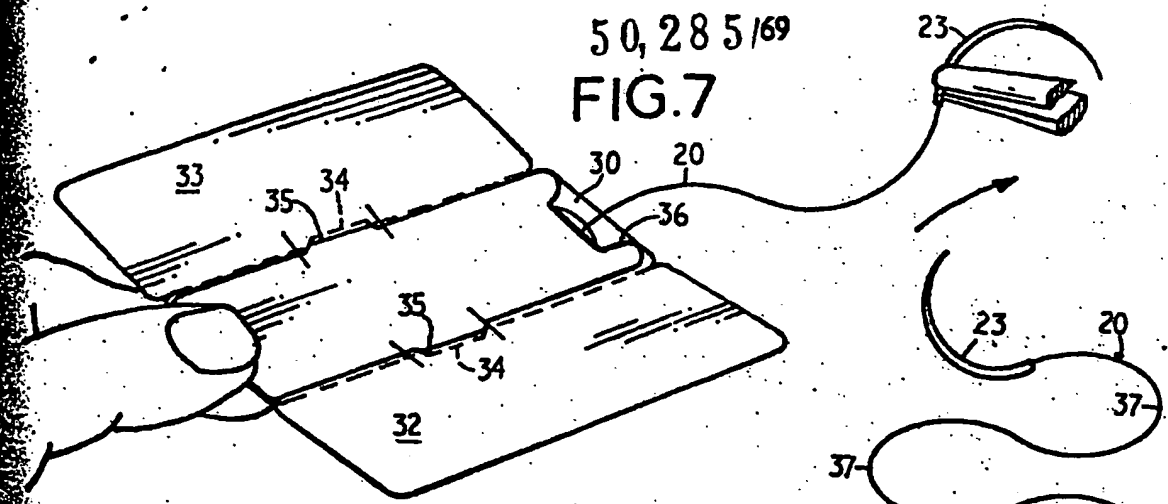


FIG.8

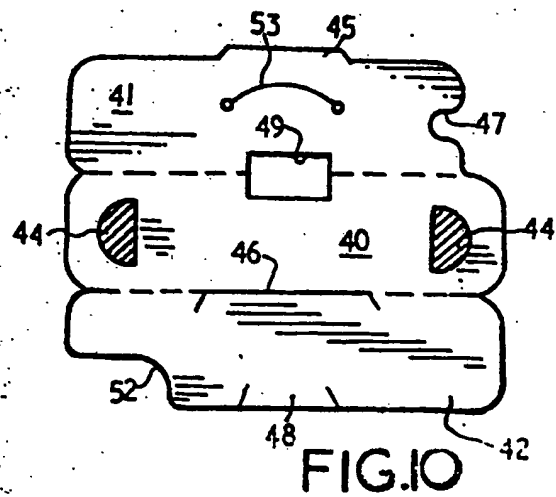
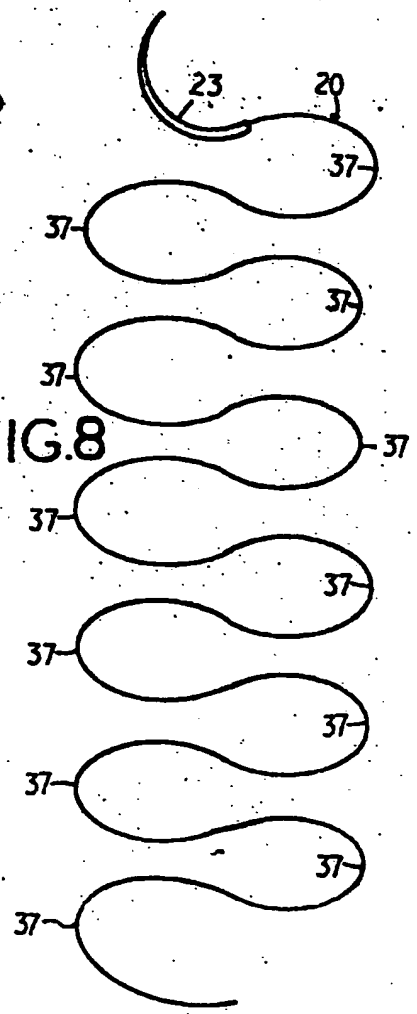


FIG.10

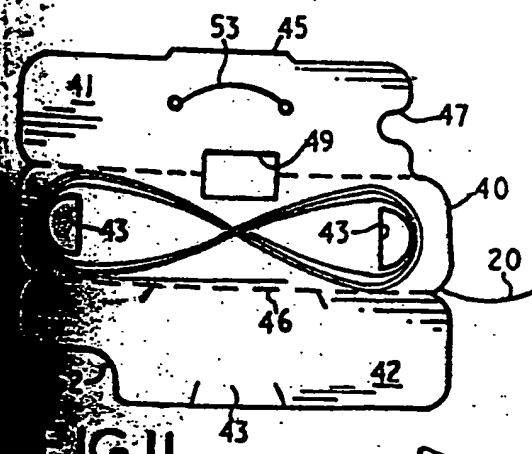


FIG.11

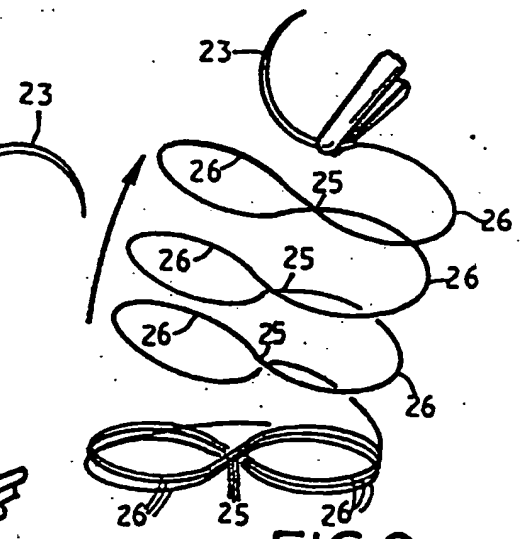


FIG.9

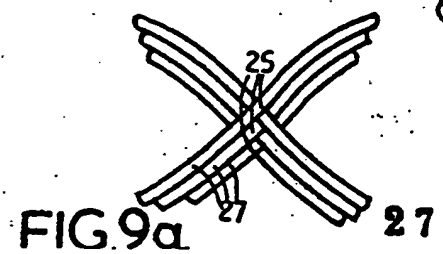


FIG.9a

440,357

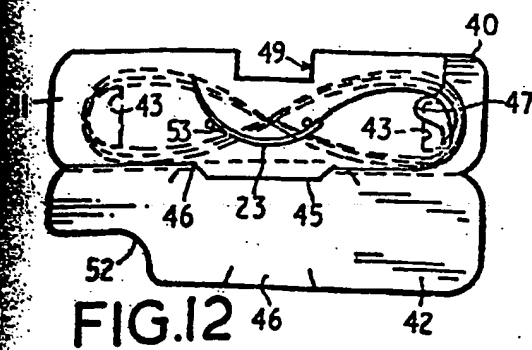


FIG. 12

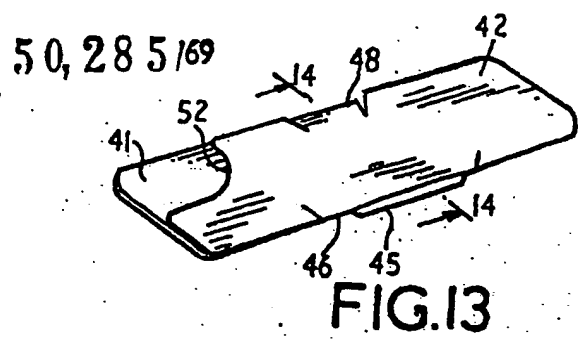


FIG. 13

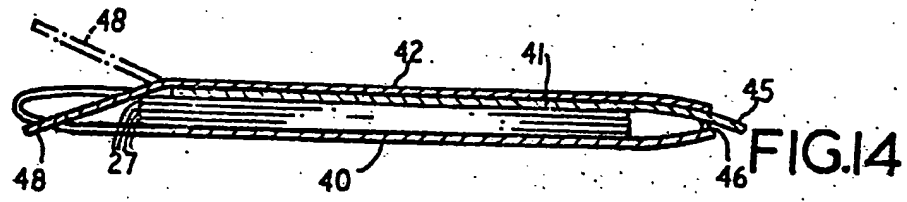


FIG. 14

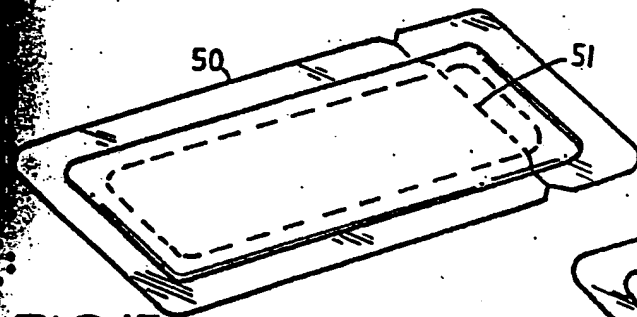


FIG. 15

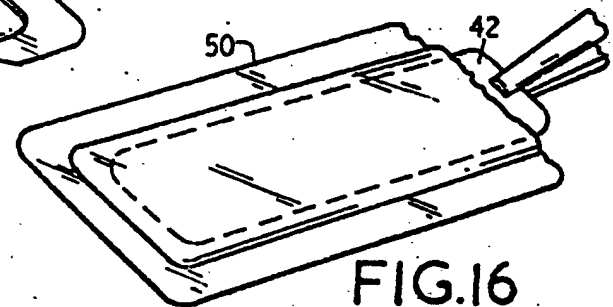


FIG. 16

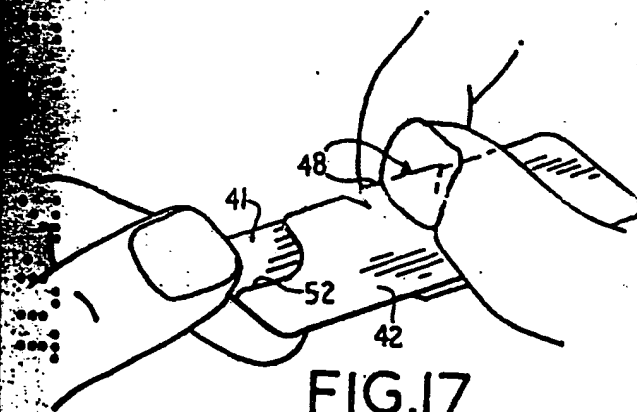


FIG. 17

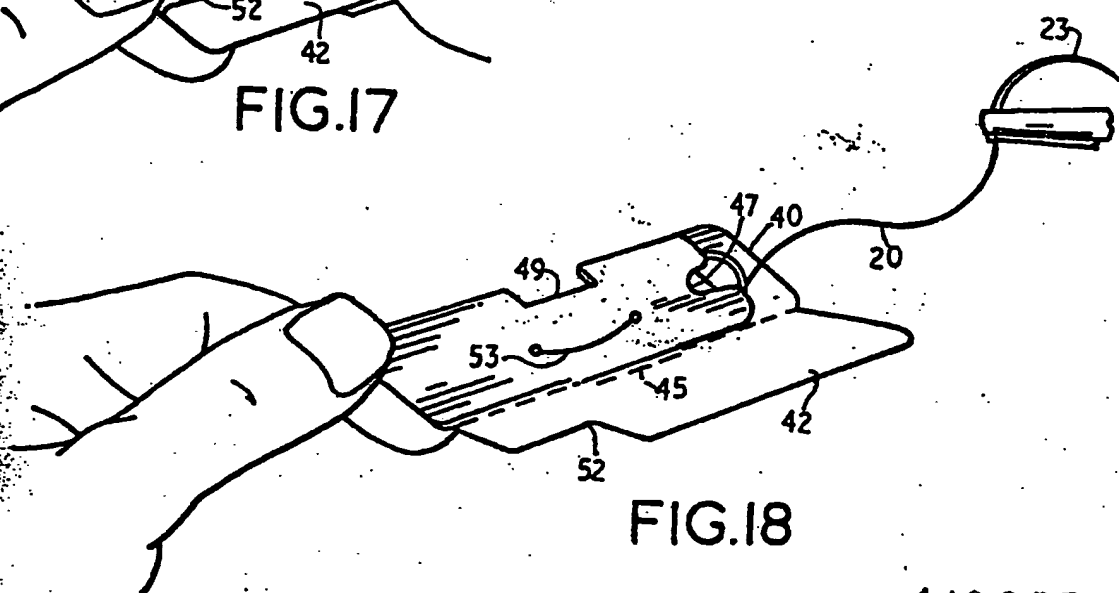


FIG. 18

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